



S/N 09/634,207

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dennis A. Carson et al. Examiner: Tamthom M. Truong
 Serial No.: 09/634,207 Group Art Unit: 1624
 Filed: August 9, 2000 Docket No.: 103.022US1
 Title: INDOLE COMPOUNDS USEFUL FOR THE TREATMENT OF CANCER

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
 Washington, D.C. 20231

Sir:

We, Dennis A. Carson, and Howard B. Cottam, declare and say:

1. I, Dennis Carson, am presently the director of The Rebecca and John Moores UCSD Cancer Center in the School of Medicine at The University of California, San Diego and a tenured professor in the Department of Medicine. I am the author of more than 500 research papers in peer-reviewed journals and books in the subjects of biochemistry, immunology, autoimmune and immunodeficiency diseases and molecular genetics, and a named inventor on 46 issued U.S. patents.

2. I, Howard B. Cottam, have been engaged in the design and synthesis of small molecules for immune modulation, antiviral, antitumor and antiparasitic use for over 20 years. These molecules are those of the carbohydrate, heterocyclic, nucleoside and nucleotide classes. I am author of more than 50 peer-reviewed journal articles and serve as an active reviewer for 8 journals. I am an inventor on 19 U.S. patents or patent applications which have issued or are pending.

3. We are named co-inventors on the above-identified patent application, and make this declaration to support our assertions and claims that the present compounds would be generally useful to treat the cancer, particularly leukemia, multiple myeloma, prostate cancer, hematopoietic cancers, cancers of the bone marrow, and cancers that express high levels of PPAR-γ 1.

4. We have reviewed U.S. Patent Application Serial No. 09/634,207, the Office Action mailed January 14, 2004, and the response filed herewith, and make this declaration in support of the patentability of the pending claims.

5. In the Office Action mailed January 14, 2004, the Examiner rejected claims 10, 12-23, and 49-54 under 35 USC § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner asserted that allegedly the claims contain subject matter

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that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. Under our direction compounds of the invention have been prepared and/or tested and are illustrated in the attached Appendix.

7. The starting materials for preparing the compounds of the invention can be prepared using compounds and methods disclosed in Demerson, U.S. Patent 3,843,681. A reduction of the acid or ester of Demerson provides a functional group (alcohol). The compounds of the invention having the -Y-Z groups can be readily prepared using routine transformations and techniques that are well known to a chemist having ordinary skill in the art starting with the alcohol compound prepared from the reduction of the Demerson acids or esters. The data indicating that the compounds are efficacious are included in the attached Appendix.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of the application or any patent issuing thereon.

7/17/04

Date

7/14/04

Date

Dennis Carson

Dennis A. Carson

Howard B. Cottam

Howard B. Cottam

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Appendix (page 1)

Compound	Structure	MW	CLL (μm)	LnCap (μM)	RPMI8226 (μM)
(R-Etololac)		287.36	174.1 (1st) 263.1 (2nd)	95 (1st) 132.0(2nd) 140 (3rd) 108.4 (4th)	250 (1st) 197.3(2nd) 250 (3rd) 139.4 (4th)
1		273.37	177.4	39.8	134.7
2		291.82	572.2	~58	~105
3		287.40	>1000		473.5
4		286.37	105 200 190 160 160	69.6	109.6
5		271.36	111.3	57	~70uM
6		257.38	>1000	340	~180
7		285.39	686.3	39.8	53.3
8		333.49	324.5	~140	121.5

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Appendix (page 2)

Compound	Structure	MW	CLL (μm)	LnCap (μM)	RPMI8226 (μM)
10		287.40	272.4	62.7	~110
11		289.38	415.8	200.9	304.9
12		275.37	767.3	~210	~190
13		270.37	714.3	~100	~270